

**REMARKS**

**Application Status and Claim Amendment**

Applicants first thank the Examiner for entering the RCE and prior claim amendments and for withdrawing all of the previous rejections to the pending claims.

Claims 16-25, 27-28, 30-31, 33, and 35 are currently pending. Applicants make two amendments to the claims, merely to re-phrase claims 16 and 35.

The amendment to claim 16 merely changes the grammatical structure of one of the clauses of the claim. The amendment to claim 35 only changes the grammatical format of "visualization" to "visualizing." The words "the multimer bands" are inserted after "visualizing" merely so that the claim has a grammatically correct structure following the change from the noun to gerund form of visualize. In any case, it is inherent from claim 16 that it is the multimer bands which are visualized. Hence, the amendment does not narrow the scope of any claim. Because those amendments merely re-word certain aspects of those two claims, they are supported by the application as a whole, introduce no new matter, and require no further search of the art. Applicants respectfully request their entry.

**Claim 35 Is Definite Regardless of Enclosed Amendment**

The Office rejects claim 35 under 35 U.S.C. § 112, second paragraph, asserting that there is no antecedent support for "the visualization." (Office Action at page 2.) Applicants traverse that rejection, but nonetheless have amended claim 35, as described above, so that the rejection is rendered moot.

Applicants reiterate that, according to the M.P.E.P., claims need only define the patentable subject matter with a degree of particularity and distinctness that is

reasonable; not exact. (M.P.E.P. § 2173.02, emphasis in original.) In addition, a lack of antecedent support taken alone is not sufficient to warrant a rejection under § 112, second paragraph. (M.P.E.P. § 2173.05(e); emphasis added.)

Indeed, in this case, independent claim 16 recites “visualizing” multimer bands, while its dependent claim 35 recites that the gel is fixed and dried before “the visualization.” It is self-evident from the claim language that “the visualization” referred to in claim 35 is the same one described in claim 16. The only difference between the two claims is that one claim uses a gerund form of visualize while the other uses the noun form. Hence, Applicants can only conclude that the Office uses an overly formalistic approach in rejecting these claims for alleged lack of definiteness.

In any event, solely to speed the prosecution, Applicants re-phrase claim 35 so that claims 35 and 16 use the same grammatical form of the word visualize. Thus, Applicants request the withdrawal of this rejection.

### **The Pending Claims Are Non-Obvious**

#### Rejection of claims 16-24, 27-28, 30-31, 33, and 35 over Shainoff in view of Bhat & Nagineni

The Office rejects claims 16-24, 27-28, 30-31, 33 and 35, contending that they are obvious under 35 U.S.C. § 103(a) over Shainoff (*Adv. Electrophoresis* 6: 65-176 (1993)) in view of Bhat & Nagineni (*Anal. Biochem.* 105: (1988)). (Office Action at pages 3-4.) Applicants traverse that rejection.

A *prima facie* case of obviousness must satisfy three requirements. See M.P.E.P. § 2143. First, there must be a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine their teachings. Second, there must be a

reasonable expectation of success in performing the combination. Finally, the cited references must teach or suggest each and every limitation of the claims. Both the motivation and the expectation of success must also be found in the references themselves or in the knowledge generally available to one of ordinary skill in the art; not in the application being examined. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); M.P.E.P. § 2142. Accordingly, the references must be viewed without the benefit of hindsight afforded by the claimed invention. M.P.E.P. § 2141.

The Shainoff and Bhat & Nagineni combination, like the others the Office has previously withdrawn, fails all of those requirements.

First, there is no motivation to combine the Shainoff and Bhat & Nagineni publications in such a way as to obtain Applicants' claimed invention. While Shainoff's Figure 4 does present a fibrinogen separation, Shainoff as a whole does not teach using agarose. In fact, the purpose of Shainoff's article is to convince researchers in the art that they should not use agarose, but should try an alternative material called glyoxyl agarose (see Title), also known as oxidized glycetyl agarose (see pages 68-69) to electrophorese proteins. As can be seen at pages 68-69 and Figures 2-3 of Shainoff, glyoxyl agarose is made from agarose through chemical transformations, it is not the same material as agarose. Thus, Shainoff teaches away from Applicants' invention.

Bhat & Nagineni would not motivate one of ordinary skill in the art to turn against Shainoff's advice and nonetheless conduct a fibrinogen separation using agarose because it does not teach separation of fibrinogen and von Willebrand factor. Instead, it describes a very different electrophoretic procedure: two-dimensional separation of different types of proteins. That is a different type of electrophoresis experiment with

different issues in terms of resolution and visualization than Applicants' multimer separation procedure. Hence, one of ordinary skill in the art would attach little weight to Bhat & Nagineni.

In addition, motivation to combine is based on what one of ordinary skill in the art, knowing nothing of the applicant's invention, would desire to do. It is not based on what is merely technically possible. See, e.g., *Winner v. Wang*, 53 U.S.P.Q.2d 1580, 1590 (Fed. Cir. 2000). One of ordinary skill reviewing the articles by Shainoff and Bhat & Nagineni would not desire to run an agarose gel of fibrinogen and von Willebrand factor proteins, thus disregarding Shainoff's advice.

For that reason alone, this is not a *prima facie* case of obviousness. But there is also no reasonable expectation of success in reviewing the Bhat & Nagineni and Shainoff articles in combination. Again, Bhat & Nagineni, shows two-dimensional separations of different kinds of proteins. Hence, there is no indication from that article that a dye-stained submarine agarose gel procedure can effectively separate and allow the visualization of fibrinogen and von Willebrand multimers. Moreover, Shainoff's Figure 4 was run using a different type of gel matrix. Thus, it is difficult to assess how a similar experiment run on agarose would appear.

Finally, Shainoff, in combination with Bhat & Nagineni, does not teach or suggest all of the elements of claim 16 as arranged in that claim. The Office contends that Shainoff teaches all of the elements of claim 16 save the submarine electrophoresis procedure. (Office Action at page 3.) But, as described above, Shainoff does not teach the use of agarose. Shainoff also does not teach whether or not the glyoxyl agarose material is homogeneous or free of lumps. Therefore, Shainoff does not teach or

suggest Applicants' claim element of a "continuous, homogeneous agarose gel free of lumps." As to the dependent claims, Applicants also point out that Shainoff, regardless of the gel matrix material used for electrophoresing fibrinogen, does not teach the gel percentages of any of claims 21-23. (See Figure 4.)

Bhat & Nagineni does not fill the gaps left by Shainoff because it also does not refer to gels that are homogeneous and free of lumps and does not mention separations of fibrinogen or von Willebrand factor.

Because this combination fails all of the requirements for a *prima facie* case of obviousness, Applicants respectfully request the Office to withdraw the rejection.

Rejection of claim 25 over Shainoff in view of Bhat & Nagineni and further in view of Perrella & Denisov

The Office rejects claim 25 as allegedly obvious over Shainoff in view of both Bhat & Nagineni and Perrella & Denisov (*Meth. Enz.* 259: 468-487 (1995).). (Office Action at page 4.) Applicants traverse that rejection for the same reasons Applicants traverse the rejections of claims 16-24, 27-28, 30-31, 33, and 35 over Shainoff and Bhat & Nagineni, as just described.

Those two publications do not teach all of the claim elements. Nor is there a motivation to combine them or a reasonable expectation of success in doing so. (See above.) Perrella & Denisov does not correct the flaws in the combination of Shainoff and Bhat & Nagineni.

Indeed, the Office relies upon Perrella & Denisov only for a teaching of running electrophoresis at the temperatures expressed in claim 25, and for contribution of no other elements of the invention as a whole. (Office Action at page 4.) Furthermore, Perrella & Denisov does not even pertain to agarose gel electrophoresis, but instead

describes two-dimensional isoelectric focusing experiments on haemoglobin samples, which are run on polyacrylamide gels. (See Perrella & Denisov at page 471, first incomplete paragraph, to page 473, second line, for example.) Those of ordinary skill in the art recognize that methods and conditions for running polyacrylamide gels, such as SDS-PAGE gels are quite different from those using agarose because the physical properties of those two gel matrix materials are very different.

Hence, Perrella & Denisov is not even in Applicants' field of endeavor or reasonably pertinent to the problem addressed by Applicant's invention. Thus, it is not properly combinable with the other articles cited here. See § 2141.01(a) of the M.P.E.P.

illustrates that differences in structure and function are key to determining whether a publication is in the field of an applicant's endeavor or pertinent to an applicant's problem. For example, in *Wang Laboratories, Inc. v. Toshiba Corp.*, 26 U.S.P.Q.2d 1767 (Fed. Cir. 1993), art discussing large computer memories was not in the same field as that discussing personal computer memories because those memories have different structures and intended uses. In *In re Clay*, 23 U.S.P.Q.2d 1058 (Fed. Cir. 1992), the invention and the cited reference used the same gel substance, but the reference used it under different temperature and pressure conditions and for a different purpose than the claimed invention (storing hydrocarbon materials rather than extracting them from the earth).

For all of the reasons above, Perrella & Denisov cannot overcome Shainoff's teaching away any more than can Bhat & Nagineni.

Accordingly, this rejection also does not satisfy the requirements for a *prima facie* case, and Applicants request its withdrawal.

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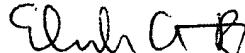
In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of all of claims 16-25, 27-28, 30-31, 33, and 35.

Please grant any extensions of time required to enter this response and charge any required fees that are not otherwise found herewith to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: September 5, 2006

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Attachment:

**Petition for One-Month Extension of Time**